Memorial Sloan Kettering Cancer Center

PATIENT & CAREGIVER EDUCATION

Clinical Trials at MSK: What You Need to Know

This information explains clinical trials, which are are research studies that test new treatments, procedures, or devices to see how well they work.

What is a clinical trial?

Clinical trials are research studies that test new treatments, procedures, or devices to see how well they work. They are an important part of helping to prevent, treat, and cure cancer. Almost every cancer treatment given to patients was first tested during a clinical trial.

Clinical trials are designed to answer specific questions about:

- Safety.
- Benefits.
- Side effects.
- Whether some people benefit more than others.

Are clinical trials safe?

Researchers are required to follow strict rules to make sure that clinical trials are as safe as possible. These rules are enforced by the federal government.

Every clinical trial is approved and monitored by an Institutional Review Board (IRB). The IRB makes sure that the risks are as low as possible and that the potential benefits outweigh the risks. IRBs include doctors, nurses, researchers, community advocates, and others who make sure that each clinical trial is ethical and fair and that your rights are protected.

Once a trial is approved by the IRB, researchers must follow a careful plan that describes exactly what will happen during the trial. This plan is called a protocol. You will know the full details of the protocol before joining any clinical trial. Learning about a trial is called informed consent, which is explained later in this resource.

What are the possible benefits of taking part in a clinical trial?

- You may get access to new drugs and other treatments, sometimes years before they are available to everyone.
- You will be closely monitored and supported by your research team.
- You will advance cancer research, which may help other people with cancer in the future.

What are the possible risks of taking part in a clinical trial?

- A clinical trial may require more time and medical attention than the usual treatment (called “standard of care,” explained later in this resource). This might include more frequent or longer doctor’s visits, phone calls, treatments, and hospital stays.
- The treatment might not work.
- The treatment might cause serious side effects.
- Even if a clinical trial helps some people, it might not help others.

What is informed consent?

Informed consent is the process of learning about the clinical trial before you decide whether or not to take part in it. A member of the research team will explain:

- The purpose of the trial.
- How long it will take.
- What will happen.
- The potential risks and benefits.
- Information about the privacy of your medical records.

That person will also give you an informed consent form to read. Once you have learned about the clinical trial and a member of the research team has answered all of your questions, you'll decide whether you want to take part in the trial. If you choose to take part, you will sign the consent form. You will take that form home with you so that you can look back at it anytime. Even though you have signed the consent form, you still have the right to leave the trial at any time and for any reason.

Informed consent continues throughout the trial. The research team will give you updates on the progress of the trial, along with any side effects or other risks that have been found.

If you prefer to learn about a clinical trial in a language other than English, just ask. MSK will provide a free interpreter for you.

What are the most common kinds of clinical trials for cancer?

- **Treatment** trials test new drugs or new combinations of drugs, new devices, and new ways of doing procedures, surgery, or radiation therapy.
- **Prevention** trials test new ways to prevent cancer in people who have never

had it, or to stop it from coming back in people who have. These may include medicines, vaccines, vitamins, or lifestyle changes.

- **Screening** trials test the best way to find cancer early, before a person has any signs of it.
- **Diagnostic** trials test ways to find cancer when a person has signs of it.
- **Quality of life** trials, which are also called **supportive care** trials, study ways to help people manage symptoms and side effects from cancer treatments.

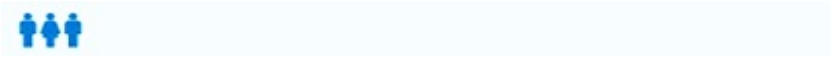
Phases of Clinical Trials

Drugs, treatments, and devices move through four different levels of testing that are called phases. Most people take part in only one phase of a trial.

Phase 1

Safety and dosage level

Tests to see if it is safe, how well it works, and what dose is most effective without serious side effects.



Size: 10 to 30 people

Phase 2

Does it work

Tests responses. Uses a method called randomization to assign people by chance to get either what is being tested, or the standard of care.



Size: Fewer than 100 people

Phase 3

Is it better than current treatment

Compares the new treatment with the standard of care. Evaluates if it is safer, whether people live longer, and if there are fewer side effects. Uses randomization method.



Size: 100s to 1,000s of people

Phase 4

Evaluates long-term safety and benefits

Tests the side effects, risks, and benefits over a long period of time. Takes place after treatment is approved by the US Food and Drug Administration (FDA).

What is randomization?

Some studies use a method called randomization to assign people in a clinical trial to a treatment group. When people are assigned at random, it means people were assigned by chance to groups that will get different treatments. For many studies, this means each person has the same chance of getting assigned to a group, like heads or tails when flipping a coin. The people taking part in studies that use randomization do not get to choose a group. This helps researchers learn which treatment is the safest and most effective.

In many phase 2 randomized clinical trials one group will get the standard of care while the other group gets the standard of care as well as the new treatment.

What is a placebo, and will I get one?

A placebo is a pill (sometimes called a "sugar pill"), a liquid, a shot, or a procedure designed to seem like a real treatment but actually isn't. Usually the person getting a placebo doesn't know it is not a real treatment. Using placebos is one of the ways researchers make sure the results of the study are accurate.

Many people think that if they take part in a clinical trial they may get a placebo. But only a few cancer clinical trials use them, and they can only be used if it's safe to do so. If a placebo is part of a trial you're thinking about taking part in, someone from the research team will explain that to you. It will also be written in the consent form.

How do I know if I can join a clinical trial?

Clinical trials have something called "eligibility criteria" that let you know who can join. Things like age, gender, sex, the type and stage of your disease, past treatment(s), and other medical conditions are common examples. Eligibility criteria help researchers keep you safe while they collect the information they need.

Can I quit a clinical trial?

Yes. You can leave a clinical trial at any time and for any reason. If you leave a clinical trial, you can still take part in other trials if you choose to.

Who takes care of me while I'm in a clinical trial?

Your MSK research team will work closely with the rest of your MSK healthcare team to coordinate your care. Your research team includes:

- **Principal Investigator (PI)**: The researcher in charge of a clinical trial.
- **Sub-Investigators**: Supervised by the PI, sub-investigators are members of the research team who perform important procedures and make key decisions.
- **Clinical Trials Nurse**: A nurse that specializes in the care of people who take

part in research.

- **Office Practice Nurse**: A nurse that works closely with your doctor and the clinical trials nurse to give you care that is not part of the clinical trial.

What questions should I ask my doctor about clinical trials?

- ☐ Why do researchers think this new treatment may be effective?
- ☐ Has this treatment been tested before?
- ☐ Have there been other trials like this one? What were the results?
- ☐ What kind of people will be in the clinical trial?
- ☐ How many people are needed for the clinical trial?
- ☐ How long will the trial take?
- ☐ Will I find out about the results of the clinical trial?
- ☐ How could this clinical trial help me?
- ☐ How will I know if the treatment is working?
- ☐ Will I have to stay in the hospital?
- ☐ Will I have to come to the hospital for treatments and tests? How often?
- ☐ Will I have to change my daily activities or my diet?
- ☐ What type of long-term follow-up care is part of this study?
- ☐ Who will pay for treatment?
- ☐ If I have questions about the trial, who can I contact?
- ☐ Can I talk to an MSK patient who has been on a clinical trial?
- ☐ Where does MSK offer clinical trials?
- ☐ What are my treatment options if I don't join the clinical trial?

If you have any other questions, you can write them below:

Where can I get more information about clinical trials?

For more information about clinical trials, talk with a member of your healthcare team or visit one of the websites listed below. They include information about how clinical trials work, how to decide if a clinical trial is right for you, and databases you can search to find a trial that may be right for you.

MSK Clinical Trials
www.mskcc.org/cancer-care/clinical-trials

National Cancer Institute
www.cancer.gov/about-cancer/treatment/clinical-trials

National Institutes of Health
www.nih.gov/health-information/nih-clinical-research-trials-you

What are some other services MSK offers?

Patient Financial Services
www.mskcc.org/insurance-assistance
The clinical trial will pay for many costs, but not for routine care. Our financial services specialists can answer insurance and payment questions.

For other MSK patient services, visit www.mskcc.org/pe/support.

What are some other terms I may hear?

Active follow-up: When researchers follow-up with people to look for changes in their health over time. This usually happens after the person in the study has completed the treatment being studied.

Adverse Event (AE): A side effect that may be related to a clinical trial drug or treatment. When someone taking part in a clinical trial has an adverse event, they must report it to the study team. Adverse events are also referred to as toxicity.

Blinding: A way to prevent people taking part in a clinical trial from knowing which study group they are in. Sometimes the doctors and the research team are also blinded from this information. This is done so that people don't influence the results, even without meaning to.

Long-term follow-up: When researchers observe a person in a study over a long period of time. This usually happens for several years after the person in the study has completed the treatment being studied, but is still being followed up with for the study.

Research Assessments: Types of tests such as blood tests, imaging (such as x-rays and CT scans) and assessment done by doctors, nurses, and other research team members. These tests may be in addition to the tests that would be done for standard care.

Screening: The process of checking to see if a person is eligible for a clinical trial. Every clinical trial has different screening and eligibility requirements. Screening begins before a person is identified as a candidate for a clinical trial. Screening continues from the time informed consent is signed until a person is registered for the clinical trial. This process may include blood tests, physical exams, imaging (such as x-rays and CT scans), or biopsies. This process may take days to weeks, depending on the trial and the person.

Sponsor: The organization or group of people who are responsible for the safety, organization, supervision, and financial support for a clinical trial. The sponsor can be an organization, such as MSK, or an industry sponsor, such as a

pharmaceutical (drug) company.

Standard of Care (SOC): Treatment that is approved for the diagnosis that is being treated. This may include an intervention that is commonly given and accepted as effective. Depending on the clinical trial, a person may get the standard of care instead of or in addition to the treatment being tested in the clinical trial.

Telemedicine visit: For some visits, your healthcare provider and clinical trials nurse can use video technology to answer your questions about the clinical trial, check how you are doing, follow-up on any symptoms or problems you have, and come up with a treatment plan. For information, go to www.mskcc.org/pe/telemedicine-visits-msk.

How can I reach my clinical trials team?

Treating physician _____
Phone _____

Study Principal Investigator _____
Phone _____

Clinical Trials Nurse _____
Phone _____

For more resources, visit www.mskcc.org/pe to search our virtual library.

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